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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,075	02/19/2002	Ronald C. Montelaro	A34001-A/072396.0222	4545

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EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/15/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

10/079,075

Applicant(s)

MONTELARO ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2003 and 13 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-41 is/are rejected.
- 7) ☒ Claim(s) 29-34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Applicants' preliminary amendment filed 13 December 2002 (Paper No. 3) as to cancellation of claims 2-7 and amendment of claims 1, 35, 40, 42, 51, 54 and 63 have been entered. Claims 1 and 3-65 are pending and examined in this Office action.

#### ***Election/Restrictions***

Applicants' election (filed 4 June 2003, Paper No. 5) of Group I, claims 1 and 8-41 without traverse is acknowledged. Claims 42-65 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention for the reasons stated above and in the restriction requirement. Therefore, claims 1 and 8-41 are under examination to the extent that they are drawn to the elected invention.

#### ***Objection to Specification/Claims***

The disclosure is objected to because of the following informalities:

(1) In page 6, line 5 of paragraph 9 [0009], "LBU" is noted to be spelled out in full for the first instance of use. See also "MTT" in page 20, line 5 of paragraph 51.

(3) In page 19, the last line of paragraph 46 [0046], " $5500^{-1} \text{ mAc}^{-1}$ " should be changed to " $5500 \text{ mol}^{-1} \text{ cm}^{-1}$ ".

(4) In claims 29, "LLP-1" should be spelled out for the first time recitation in the claims. Also, in claims 29-34, "An" before LLP-1 should be changed to "a".

Corresponding correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26-34 and 38-39 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1 and 26 and their dependent claims thereof, as written, do not sufficiently distinguish over other polypeptide, proteins and enzymes as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "synthesized" or "purified" as disclosed on [0077] of the specification. See MPEP 2105.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-34 and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-34 are indefinite in the recitation "LLP-1 peptide" because it is unclear as to whether or not "LLP" refers to tripeptide sequence Leu-Leu-Pro.

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Claim 34 recites "additional residues"; the recitation is not apparent as to which amino acid residues the additional residues are compared.

Claim 38 recites "at least one cysteine residue" which render the claim indefinite since SEQ ID NOs: 4-12 peptides contain no cysteine residues recited in claim 1 from which claim 38 depends.

Claim 39 is indefinite in "a disulfide linked dimeric peptide" because (i) the peptides recited in claim 1 from which claim 42 depends contain no cysteine residues; thus, there is no molecule basis forming the said disulfide linkage; and (ii) the term "dimeric" is unclear with regard to whether or no the dimer refers to homodimer (forming intermolecular disulfide linkage between the same molecules) or heterodimer (forming disulfide linkage between different molecules).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

Claims 29-34 are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of antimicrobial peptides of SEQ ID NOs:4-12. Applicant is not in possession of any peptide analog in claims 29-34 derived from lentiviral lytic peptide 1

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(LLP-1); any LLP-1 peptide analog comprising additional residues to increase the peptide length (see claim 34).

The peptide analogs encompass the structural alterations (variants): substitutions: rearrangements, deletions, additions and/or chemical modifications in the amino acid sequence of parent peptides (see the specification [0037]). There is insufficient written description about how to make bioactive variants, e.g., rearrangement and chemical modification without deviated from a core motif structure, which has not been described in the specification. Applicant has disclosed only peptide sequences of SEQ ID NOs:4-12; therefore, the skilled artisan cannot envision all the contemplated polypeptide sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column). Further, the specification fails to describe additional representative species of peptide analogs mentioned above.

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Given the lack of a written description of *any* additional representative species comprising one of SEQ ID NOs:4-12, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative member of species to describe the genus. Thus applicant was not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

***Provisional Rejection, 35 U.S.C. 101, Double Patenting***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

A rejection based on double patenting of the “same invention” type finds its support in the language of 35 U.S.C. 101 which states that “whoever invents or discovers any new and useful process... may obtain a patent therefor...” (Emphasis added). Thus, the term “same invention,” in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*,

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151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 8-34, 35 and 36-41 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1,2-28, 29 and 39-44 of copending application No. 09785058, respectively. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



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*SWL*

Samuel Wei Liu, PhD.

July 2, 2002

*Christopher S. F. Low*

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